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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/585,830

07/12/2006

Dramane I. Laine

PU60660

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04/29/2009

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CORPORATE INTELLECTUAL PROPERTY-US, UW2220
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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

04/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/585,830 | Applicant(s) LAINE ET AL. | |
| | Examiner SHIRLEY V. GEMBEH | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/29/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6 and 13-38 is/are pending in the application.
- 4a) Of the above claim(s) 3,15,16,18 and 25-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,13,17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 3, 6 and 13-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/21/09;5/22/07;7/12/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Election/Restrictions

1. Applicant's election without traverse of Group I claims 1, 6, 13-14, 17 and 19-24 in the reply filed on 1/21/09 is acknowledged. Applicant elected a quaternary salt form of the original formula (I) compounds, e.g. wherein R1 and R2 are both methyl. A specific species is that of Example 97 wherein R3 is hydrogen; R4 and R5 are hydrogen or halogen; and R6, R7 and R8 are independently selected from hydrogen or halogen and n is 0 is acknowledged.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 1/21/09; 5/22/07 and 7/21/06 are acknowledged and has been reviewed.

Status of Claims

3. Claims 1, 3, 6 and 13-38 are pending. Claims 1, 6, 13-14, 17 and 19-24 are elected. Claims 3, 15-16, 18 and 25-38 are withdrawn due to non-elected species from the restriction requirement.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

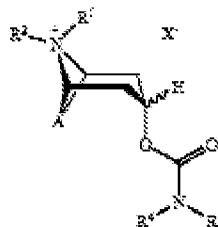
USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

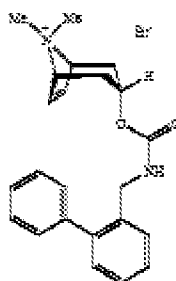
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 13, 17 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breitfelder et al. (US 7,041, 674; filing date of 11/20/03).



Breitfelder et al. teaches compound of formula 1 wherein R1 and R2 are both methyl groups. A specific species is disclosed in Example 97 wherein R3 is hydrogen; R4 and R5 are hydrogen or halogen; and R6, R7 and R8 are independently



selected from hydrogen or halogen (i.e.,), H is a hydrogen as illustrated by the formula and X⁻ is a physiological acceptable anion Br⁻ (as in instant claims 1, 13, and 20-24, see col. 23, lines 20-39). Breitfelder et al. teach these compounds are employed as pharmaceutical compositions (see col. 1, lines 27-28) with a pharmaceutically acceptable carrier (see col. col. 31, lines1-5 as required by instant claim 6). From the compound structure of Breitfelder et al. above R3 is a hydrogen (as in claim 17).

However, Brietfelder fails to teach formula I wherein n is 1.

While Brietfelder et al. do not explicitly teach such a modification wherein n equals 1, it would have been obvious to one of ordinary skill in the art to make homolog (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) of sufficiently close structural similarity, wherein there is an

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expectation that such compounds possess similar properties. It would have been obvious to one skilled in the art at the time the invention was made to modify the closest compound of Brietfelder by extending the carbon linkage at the oxygen linkage via the addition of a methyl group and in so doing obtain additional compounds for the uses taught by Brietfelder et al in view of the close structural similarity outlined above.

A prima facie case of obviousness may be based solely upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. In re Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995). The necessary motivation to make the claimed compound, and thus the prima facie case of obviousness, arises from the reasonable expectation that compounds similar in structure will have similar properties. In re Gyurik, 596 F.2d 1012, 1018 (1979). A prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (discussed in more detail below) and In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991) (discussed below and in MPEP § 2144) for an extensive review of the case law pertaining to obviousness based on close structural similarity of chemical compounds. See also MPEP § 2144.08, paragraph II.A.4.(c).

Double Patenting

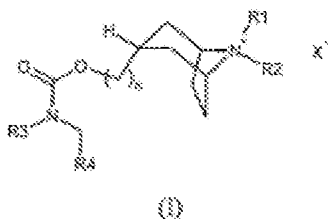
5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6, 13-14, 17 and 19-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-2, 5-10** of U.S. Patent Application No. **10599717 ('717)**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

Both sets of claims in '717 and the instant application encompass the same



compounds having a generic formula

wherein R3 and R4

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maybe a benzene ring and R 1 and R2 may be an alkyl selected from C1-C10 alkyl and n is from 0-2. Thus the current application claims are obvious of the copending application '717 claims.

In view of the foregoing, the copending application claims and the current application claims are obvious variations of each other.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
4/14/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649